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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,637	12/22/1999	MARSHA A. MOSES	CMZ-083PCPN	5202

7590

03/23/2004

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/469,637

Applicant(s)

MOSES ET AL.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-46, 49, 56-63, 130 and 149-180 is/are pending in the application.
- 4a) Of the above claim(s) 35-46, 49 and 56-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 130 149-180 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- _____ Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment, IDS and associated documents, Terminal Disclaimer, Declaration by Marsha Moses, Change in Address, Change in Power of Attorney received 1/15/04 and the IDS received 12/19/03 have been entered. Claims 35-46, 49, 56-63 are non-elected without traverse, claims 130, 149-180 are considered here. Please update the specification concerning related cases. The amended abstract is acceptable.

In view of the arguments presented and amendments to the claims, all rejections of record in the Office Action of 7/11/03 are hereby withdrawn.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 130, 149-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Howard in view of Davies.

Howard (Proc American Assoc Cancer Res) entitled "Presence of Matrix Metaloproteinases in the Urine From Bladder Cancer Patients" teaches in the abstract, MMP's correlate their presence in urine with different stages of bladder cancer. Analyzed by gelatin and casein zymography, we were able to identify several MMP's in urine and gelatinase B (92 kDa) is associated with an invasive phenotype.

The claims differ from Howard in that they specify broader cancers of epithelial origin, and MMP's of varying weights. Further, Howard is directed to staging bladder cancer and the present claims are directed to "facilitating diagnosis of cancer".

Davies (Cancer Research) entitled "Levels of MMP's in Bladder Cancer Correlate with Tumor Grade and Invasion" teaches in the abstract, zymography measured two MMP's in cells from biopsies of bladder carcinoma and normal bladder. MMP-9 was higher in tumor compared with normal samples and MMP-2 increased with tumor grade. On page 5365 first column, MMP-2 (72 kDa) and MMP-9 (92 kDa) are expressed in a variety of tumor types including skin, colon, breast and prostate. On page 5368 first column first few lines bridging to second column, MMP-9 was higher in grade III breast cancer tumors compared with benign and normal tissues.

It would have been obvious to one of ordinary skill in this art at the time this invention was made to assay MMP's in urine as taught by Howard to detect cancers other than bladder because Davies teaches the same MMP's are known to be found in other epithelial cancers. The presently claimed MMP's encompass those of Davies. Regarding diagnosing cancer, Davies shows a correlation between elevation of MMP's and various types of malignancies vs no elevation and benign or normal tissue. Further, if two known MMP's are known to be associated with malignancies, one would expect other closely related MMP's, such as in present claim 180, to also be related in the same fashion. No unexpected results are seen.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

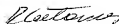
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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